

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

December 6, 2001

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Dishwasher Magic**

DP Barcode: 277786
Manufacturing-use [] OR

Reg. No. Or File Symbol: 74286-R
End-use Product [X]

TO: Adam Heyward/Drusilla Copeland
PM Team 34

FROM: Nancy Whyte, Chemist *Now*
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

[Handwritten signature: K. P. Hicks]
12/12/01

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation
Active Ingredient(s)

% by wt.

Citric acid

25.0%

BACKGROUND:

This is a new product registration application for a product used to clean and remove lime scale, soap scum, grease, iron, and other stains from an empty dishwasher. The initial review of the submission was conducted by Oak Ridge National Laboratories. Product chemistry data to satisfy registration requirements were contained in three documents (MRID Nos 454814-01, 454875-01 and -02).

FINDINGS:

- 1 The source of the active ingredient citric acid is unregistered. There was no five-batch certificate of analysis submitted with the product chemistry data, so the concentration of the purchased active ingredient is unknown.
2. The fragrance [REDACTED] has not been approved for use in pesticides. Attempts to contact the registrant's consultant to obtain the information were unsuccessful. The phone number of the person signing the Confidential Statement of Formula listed on the Confidential Statement of Formula was incorrect.
3. There appears to be a typographical error in the listing of the lower certified limit of the fragrance which is given as [REDACTED]. The correct figure should be [REDACTED].

With the exception of the certificate of analysis of the active ingredient, the product chemistry data required for registration by 830 Series Guidelines, Part B (physical and chemical characteristics) are complete. See summary of data attached below.

RECOMMENDATIONS:

1. The registrant must submit the certificate of analysis for the active ingredient from any and all suppliers to the Agency for inclusion in the product chemistry data.
2. The error in the listing on the Confidential Statement of Formula of the lower certified limit of the fragrance must be corrected.
3. The supplier of the fragrance must submit to the Agency the following information:
 - a. The complete chemical identification of all components in the ingredient,
 - b. The CAS numbers of each of the components, and
 - c. The percentage of each component contained in the ingredient (total must equal 100%).

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system ☒ [X]
- Are all TGAI used registered? Yes ☐ No ☒ [X]
- Integrated formulation system ☐ []
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:

Cleared for food use under 40 CFR §180.1001: Yes ☐ No ☒ [X] NA ☐ []

4c. Physical state of product:

4d. The chemical IDs and analytical information (including that for the TGAI), density, pH, and flammability are consistent with that given in 830.1000, Series A and 830.7300, .7000 and .6315 respectively: Yes ☐ No ☒ [X]

4h. NCs and CLs are acceptable: ☐ Not acceptable ☒ [X]
All approved except fragrance

4i. Active ingredient (s)	NC	UCL	LCL
Citric acid	25.0%	25.75%	24.25%

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
Yes ☐ No ☐ Not applicable ☒ [X]
- All impurities of $\geq 0.1\%$ in the product have been identified?
Yes ☐ No ☐ Not applicable ☒ [X]

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes ☒ No ☐ []

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes ☐ No ☒ [X]
- 1.0% or more of methyl alcohol: Yes ☐ No ☒ [X]

- Sodium nitrite at any level: Yes [] No [X]
- a toxic List 1 inert at any level: Yes [] No [X]
- arsenic in any form: Yes [] No [X]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [] No [] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [] No [] Not applicable [X]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [X] No []

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [] No [X]

PRODUCT CHEMISTRY (Series 830 Part A)

	Acceptance of Information	MRID No.
830.1550 Chemical ID (See Appendix) ¹	A	454814-01
830.1600 Description of Materials	A	454814-01
830.1620 Manufacturing Process ²	A	454814-01
830.1650 Formulation Method ³	NR	
830.1670 Discussion of Impurities ⁴	NR	
830.1700 Analysis ⁵	A	Reregistration document
830.1750 Certified Limits ⁶	NA	CSF
830.1800 Analytical Method for AIs ⁷	Acid-base titration	454814-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required, G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLS recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR),

Physical and Chemical Characteristics (Series 830, Part B)

6b. <u>Physical/Chemical Properties*</u>	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Clear and colorless	454814-02
830.6303 Physical State	A	Liquid	454814-02
830.6304 Odor	NR		
830.6314 Oxidation/Reduction	A	Contains no oxidizer or reducing agents	454814-02
830.6315 Flammability/Flash Pt	NA	Does not contain flammable components	454814-01
830.6316 Explodability	NA	Not explosive	454814-02
830.6317 Storage Stability	A	Pending	454814-02
830.6320 Corrosion Character.	A	Pending	454814-02
830.7000 pH	A	2.2 +/- 0.01 1% aqueous	454814-02
830.7100 Viscosity	A	2.117 cP	454814-02
830.7300 Density/sp. gravity	A	1.109 gm/mL	454814-02

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= Not required
G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc;
Unless otherwise indicated, the property should be at 25°C.

DATA EVALUATION RECORD

CITRIC ACID (DISHWASHER MAGIC)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Beginning Materials (OPPTS 830.1600)
Description of Formulation Process (OPPTS 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis, Certified Limits (OPPTS 830.1700, 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRIDs 45481401, 45481402, 45481403, 45487501

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Work Assignment No. K351

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Quality Assurance:
Lee Ann Wilson, M.A.

Signature: Eric B. Lewis
Date: OCT 16 2001
Signature: Sylvia Milanez
Date: OCT 16 2001
Signature: Robert H. Ross
Date: OCT 16 2001
Signature: L. A. Wilson
Date: OCT 16 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

CITRIC ACID

MRIDs 45481401, 45481402, 45481403, 45487501

Product Identity and Composition (OPPTS 830.1550)
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EPA Reviewer: Nancy Whyte, Ph.D.

_____ Date: _____

EPA Work Assignment Manager:

Bonaventure Akinlosotu, Ph.D.

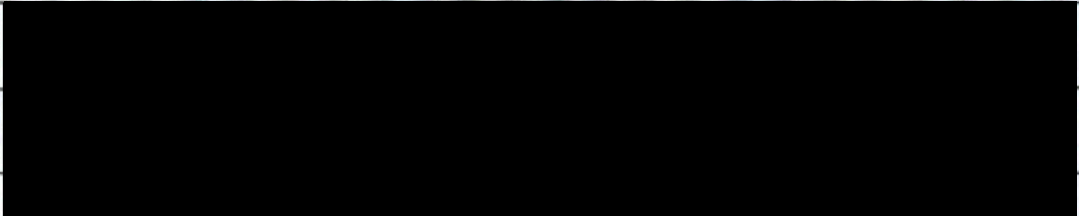
_____ Date: _____

Antimicrobials Division (7510W)

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CASE NO.: 071137P.C. CODE: 021801

Active Ingredients	P.C. Code	CAS No.
Citric acid	021801	77-92-9
Inerts		
		

DP BARCODE: D277786SUBMISSION: S603153MRID NO.: 45481401, 45481402, 45481403, 45487501TEST MATERIAL: Dishwasher Magic; active ingredient is citric acid (25.0%).

Inert ingredient information may be entitled to confidential treatment

CITRIC ACID

MRIDs 45481401, 45481402, 45481403, 45487501

Product Identity and Composition (OPPTS 830.1550)
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SYNONYMS: None

STUDY/REPORT NUMBER: MRID 45481401: WRA-01-001; MRID 45481402: WRA-01-002; MRID 45481403: WRA-01-003; MRID 45487501: 10667

SPONSOR: Dishwasher Magic, 511 Wyckoff Avenue, Wyckoff, NJ 07461

TESTING FACILITY: MRIDs 45481401-45481403: Wagner Regulatory Associates, Inc., P.O. Box 7954, Wilmington, DE 19803; MRID 45487501: Product Safety Labs, 2394 Route 130, Dayton, NJ 08810

TITLE OF REPORT: MRID 45481401: Product Identity, Composition, Analysis

MRID 45481402: Physical/Chemical Properties

MRID 45481403: Physical/Chemical Properties of Dishwasher Magic

MRID 45487501: Physical and Chemical Characteristics: Physical State, pH, Viscosity and Density/Relative Density

AUTHOR: MRIDs 45481401-45481403: J.M. Wagner

MRID 45487501: C. Wo

REPORT ISSUED: MRIDs 45481401- 45481403, 45487501: August 10, 2001

EXECUTIVE SUMMARY: The product identity and composition, beginning materials, formulation process, discussion of impurities, certified limits, preliminary analysis, and physical/chemical characteristics for Dishwasher Magic are addressed in MRIDs 45481401, 45481402, 45481403, and 45487501. Dishwasher Magic is an end-use product used to remove lime scale, calcium, soap scum, grease, and iron from the inside of dishwashing machines. The active ingredient is citric acid (nominal concentration of 25.0%, certified lower-upper limits of 24.25-25.75%). The inert ingredients are [REDACTED]

[REDACTED] A CSF and a product label were provided. An MSDS was supplied for each of the active and inert ingredients (except [REDACTED]). Dishwasher Magic is formulated in a batch process that is a simple mixing of the active and inert ingredients, and no impurities are expected to be formed. The certified limits for the ingredients are within OPPTS recommended guidelines, assuming that the lower limit given on the CSF for the [REDACTED] is a typographical error. A preliminary analysis was not required because the product is not formulated by an integrated system. The physical/chemical characteristics were adequately addressed.

CITRIC ACID

MRIDs 45481401, 45481402, 45481403, 45487501

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Discussion of Formation of Impurities (OPPTS 830.1670)
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Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

Classification of the studies:

Product Identity and Composition (OPPTS 830.1550)- **Acceptable**

Description of Beginning Materials (OPPTS 830.1600)- **Acceptable**

Description of Formulation Process (OPPTS 830.1650)- **Acceptable**

Discussion of Formation of Impurities (OPPTS 830.1670)- **Acceptable**

Preliminary Analysis (OPPTS 830.1700)- **Acceptable**

Certified Limits (OPPTS 830.1750)- **Acceptable**, provided the lower limit for [REDACTED]

[REDACTED] is corrected on the CSF.

Enforcement Analytical Method (OPPTS 830.1800)- **Unacceptable**, but upgradeable upon submission of an acceptable method.

Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)- **Acceptable**, provided acceptable results of the storage stability/corrosion characteristics study are submitted at its conclusion.

COMPLIANCE: Signed and dated Data Confidentiality Statements and GLP compliance statements were provided for each MRID. A Quality Assurance Statement was provided for MRID 45487501.

A. PRODUCT IDENTITY AND COMPOSITION (OPPTS 830.1550)

Dishwasher Magic is an end-use product used to remove lime scale, calcium, soap scum, grease, and iron from the inside of dishwashing machines. The product claims to kill 99.9% of *Salmonella* and *E. coli* inside dishwashers. The active ingredient is citric acid (CAS No. 77-92-9, nominal concentration of 25.0%). The inert ingredients are [REDACTED]

[REDACTED] A CSF and a product label were provided.

B. DESCRIPTION OF BEGINNING MATERIALS AND FORMULATION PROCESS (OPPTS 830.1600 AND OPPTS 830.1650)

The beginning materials used to formulate Dishwasher Magic are citric acid, [REDACTED]

[REDACTED]

Inert ingredient information may be entitled to confidential treatment

CITRIC ACID

MRIDs 45481401, 45481402, 45481403, 45487501

Product Identity and Composition (OPPTS 830.1550)
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An MSDS was submitted for the inert ingredients (except [REDACTED]). Suppliers for all the beginning materials (except [REDACTED]) were identified on the CSF.

C. DISCUSSION OF FORMATION OF IMPURITIES (OPPTS 830.1670)

The formulation process is a simple blending of the active and inert ingredients. No chemical reactions are expected to occur, and no impurities are expected to be formed.

D. PRELIMINARY ANALYSIS (OPPTS 830.1700)

Preliminary analysis is not required, since the product is formulated by a non-integrated system. Although citric acid is not an EPA-registered product, it is GRAS per 21 CFR 182 and EPA has approved its use.

E. CERTIFIED LIMITS (OPPTS 830.1750)

The active ingredient in Dishwasher Magic is citric acid, which is present at a nominal concentration of 25.0%, with certified lower-upper limits of 24.25-25.75%. The inert ingredients are [REDACTED]

[REDACTED] The lower certified limit given on the CSF for [REDACTED] is incorrect, apparently a typographical error. Assuming the correct lower limit is [REDACTED], all the certified limits are within the range recommended by OPPTS guidelines.

F. ENFORCEMENT ANALYTICAL METHOD (OPPTS 830.1800)

The enforcement analytical method was not identified. Page 5 of the confidential attachment to MRID 45481401 states that after formulation of the product, the citric acid content is [REDACTED] but no details were provided. Page 6 of MRID 45481401, under the heading of Enforcement Analytical Method, gives no method but cites the EPA RED for citric acid (June 1992), which was included in the submission. Page 4 of the RED states that analysis of citric acid can be accomplished by liquid chromatography.

G. PHYSICAL AND CHEMICAL CHARACTERISTICS (OPPTS 830.6302-830.7950)

Color (830.6302): Clear, colorless.

Physical State (830.6303): Liquid.

Odor (830.6304): Not provided, and not required per PR Notice 92-5.

Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

CITRIC ACID

MRIDs 45481401, 45481402, 45481403, 45487501

Product Identity and Composition (OPPTS 830.1550)
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Melting Point (830.7200): Not applicable, product is a liquid.

Boiling Point (830.7220): Not required for end-use products.

Density (830.7300): 1.109 g/mL @ 20°C (Reischauer specific gravity bottle).

Solubility (830.7840): Not required for end-use products.

Vapor Pressure (830.7950): Not required for end-use products.

Dissociation Constant (830.7370): Not required for end-use products.

Octanol/Water Coefficient (830.7570): Not required for end-use products.

pH (830.7000): 2.22±0.01 (1% w/w in deionized water @ 25°C) (VWR pH meter)

Stability (830.6313): Not required for end-use products

Oxidizing/reducing action: chemical incompatibility (830.6314): None of the components is known to be an oxidizing or reducing agent.

Flammability (830.6315): Not applicable, product does not contain combustible liquids.

Explosibility (830.6316): Not applicable, none of the components is known to be explosive.

Storage stability (830.6317): Not provided. The applicant states that a storage stability study has been initiated and results will be submitted upon completion.

Viscosity (830.7100): 2.117 cP @ 20°C (C.F. Opaque Viscometer, size 50)

Miscibility (830.6319): Not applicable, product is not intended to be diluted with petroleum solvents.

Corrosion characteristics (830.6320): Not provided. The applicant states that a corrosion characteristics study has been initiated as part of the storage stability study, and results will be submitted upon completion.

Dielectric breakdown voltage (830.6321): Not applicable, product is not intended for use around electrical equipment.

UV/Visible Absorption (830.7050): Not required for end-use products.

CITRIC ACID

MRIDs 45481401, 45481402, 45481403, 45487501

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H. DISCUSSION

The product identity and composition, beginning materials, formulation process, discussion of impurities, certified limits, preliminary analysis, and physical/chemical characteristics for Dishwasher Magic are addressed in MRIDs 45481401, 45481402, 45481403, and 45487501. Dishwasher Magic is an end-use product to remove lime scale, calcium, soap scum, grease, and iron from the inside of dishwashing machines. The active ingredient is citric acid (nominal concentration of 25.0%, certified lower-upper limits of 24.25-25.75%). The inert ingredients are [REDACTED]

[REDACTED] A CSF and a product label were provided. An MSDS was supplied for the inerts (except [REDACTED]). Dishwasher Magic is formulated in a batch process that is a simple mixing of the active and inert ingredients, and no impurities are expected to be formed. The certified limits for the ingredients are within OPPTS recommended guidelines, although the lower limit for the [REDACTED] is incorrect on the CSF, apparently a typographical error. A preliminary analysis is not required and was not submitted. No enforcement analytical method was identified. The physical/chemical characteristics were adequately addressed.

Classification of studies:

Product Identity and Composition (OPPTS 830.1550)- **Acceptable**

Description of Beginning Materials (OPPTS 830.1600)- **Acceptable**

Description of Formulation Process (OPPTS 830.1650)- **Acceptable**

Discussion of Formation of Impurities (OPPTS 830.1670)- **Acceptable**

Preliminary Analysis (OPPTS 830.1700)- **Acceptable**

Certified Limits (OPPTS 830.1750)- **Acceptable**, provided the lower limit for [REDACTED] is corrected on the CSF.

Enforcement Analytical Method (OPPTS 830.1800)- **Unacceptable**, but upgradeable provided an acceptable method is submitted.

Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)-**Acceptable**, provided acceptable results of the storage stability/corrosion characteristics study are submitted at its conclusion.

I. STUDY DEFICIENCIES

No information identifying the enforcement analytical method was submitted.